Claims 24-49 are subject to restriction. The Examiner has determined that the claimed subject matter constitutes two distinct inventions. The following two groups of claims have been identified under this restriction requirement:

I. Claims 24-33 and 41-49, directed to a method of detecting Mycobacteria comprising detecting antibodies to polypeptides; and

II. Claims 34-40, directed to a method of detecting Mycobacteria comprising detecting nucleic acids.

Applicants hereby elect Group I, namely Claims 24-33 and 41-49, for further prosecution. Furthermore, applicants object to the present restriction requirement as being unnecessary.

According to MPEP § 803, "If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions." The two inventions have the same classification, i.e., they are both in class 435. Furthermore, the area of Mycobacteria detection in biological samples is not vast. Therefore, the volume of references the Examiner is likely to need to review will not be extensive. Finally, the related parent applications have provided substantial opportunities for searching subject matter related to Mycobacteria, and additional relevant references beyond those already cited will be few, if any. Applicants are not aware of any relevant references not already cited in the Information Disclosure Statement.

Based on the discussion above, Applicants submit that examination of all of the pending claims on the merits will not pose a serious burden. Therefore, Applicants

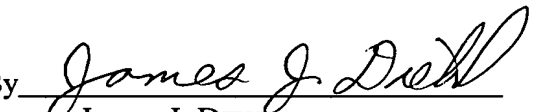
respectfully request that this Restriction Requirement under 35 U.S.C. § 121 be withdrawn.

Applicants submit that the claims are in form for examination on the merits and subsequent allowance. Early notice of such allowance is hereby requested. If the Examiner believes there are any remaining issues that may be addressed by telephone, she is requested to contact the undersigned attorney at (415) 781-1989.

Respectfully submitted,

FLEHR HOHBACH TEST
ALBRITTON & HERBERT LLP

Dated: 20 December 2000

By 
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APPENDIX

24. A method of detecting the presence of antibodies to Mycobacterium in a biological sample, said method comprising:

combining said sample with a protein having the amino acid sequence of SEQ ID NO:2, a homolog thereof or an antigenic determinant thereof; and

detecting antibodies bound to said protein.

25. The method of Claim 24, wherein said Mycobacterium is selected from the group consisting of *M. bovis, M. tuberculosis, M. leprae, M. africanum, M. microti, M. avium, M. intracellulare* and *M. scrofulaceum.*

26. The method of Claim 24, wherein said protein is immobilized on a solid support.

27. The method of Claim 26, wherein said solid support is nitrocellulose.

28. The method of Claim 24, wherein said sample comprises one or more of sputum, blood, and serum.

29. The method of Claim 24, wherein said detecting is by a qualitative detection system.

30. The method of Claim 29, wherein said qualitative detection system is a horseradish peroxidase-protein A detection system.

31. The method of Claim 24, wherein said detecting is by a quantitative detection system.

32. The method of Claim 31, wherein said quantitative detection system is a radioimmunoassay.

33. The method of Claim 24, further comprising:

combining a control biological sample with said protein; and

comparing the detection of said binding to the binding of antibodies in the control sample with said protein.

34. A method of detecting the presence of Mycobacterial nucleic acid in a sample, said method comprising:

combining a nucleic acid sample with a probe nucleic acid which hybridizes with the sequence of SEQ ID NO:1 or its complement; and

detecting nucleic acid hybridized with said probe.

35. The method of Claim 34, wherein said Mycobacterium is selected from the group consisting of *M. bovis, M. tuberculosis, M. leprae, M. africanum, M. microti, M. avium, M. intracellulare* and *M. scrofulaceum.*

36. The method of Claim 34, wherein said sample comprises mammalian cells and/or body fluid.

37. The method of Claim 34, wherein said probe nucleic acid hybridizes with single 3.25 kb BamH I fragments from *M. bovis* BCG and *M. tuberculosis* H37Rv DNA, but not BamH I-digested DA from either *M. smegmatis* or *M. vaccae.*

38. The method of Claim 34, wherein said detecting is by Southern Blot.

39. The method of Claim 34, wherein said Mycobacterial nucleic acid is amplified by Polymerase Chain Reaction.

40. The method of Claim 39, wherein said amplification uses primers derived from the sequence of SEQ ID NO:1 or homolog thereof.

41. A method of detecting the presence of Mycobacterium in a biological sample, said method comprising;

lysing the cells in said sample;

combining said lysate with antibodies to a protein having the amino acid sequence of SEQ ID NO:2 or an antigenic determinant thereof; and

detecting said antibodies bound to protein in said lysate.

42. The method of Claim 41, wherein said Mycobacterium is selected from the group consisting of *M. bovis, M. tuberculosis, M. leprae, M. africanum, M. microti, M. avium, M. intracellulare* and *M. scrofulaceum.*

43. The method of Claim 41, wherein said lysate is immobilized on a solid support.

44. The method of Claim 43, wherein said solid support is nitrocellulose.

45. The method of Claim 41, wherein said detecting is by a qualitative detection system.

46. The method of Claim 45, wherein said qualitative detection system is a horseradish peroxidase-protein A detection system.

47. The method of Claim 41, wherein said detecting is by a quantitative detection system.

48. The method of Claim 47, wherein said quantitative detection system is a radioimmunoassay.

49. The method of Claim 41, further comprising:
culturing a diagnostic sample to produce colonies of bacteria present therein, whereby said culture represents said biological sample.

APPENDIX

24. A method of detecting the presence of antibodies to Mycobacterium in a biological sample, said method comprising:

combining said sample with a protein having the amino acid sequence of SEQ ID NO:2, a homolog thereof or an antigenic determinant thereof; and

detecting antibodies bound to said protein.

25. The method of Claim 24, wherein said Mycobacterium is selected from the group consisting of *M. bovis, M. tuberculosis, M. leprae, M. africanum, M. microti, M. avium, M. intracellulare* and *M. scrofulaceum*.

26. The method of Claim 24, wherein said protein is immobilized on a solid support.

27. The method of Claim 26, wherein said solid support is nitrocellulose.

28. The method of Claim 24, wherein said sample comprises one or more of sputum, blood, and serum.

29. The method of Claim 24, wherein said detecting is by a qualitative detection system.

30. The method of Claim 29, wherein said qualitative detection system is a horseradish peroxidase-protein A detection system.

31. The method of Claim 24, wherein said detecting is by a quantitative detection system.

32. The method of Claim 31, wherein said quantitative detection system is a radioimmunoassay.

33. The method of Claim 24, further comprising:

combining a control biological sample with said protein; and

comparing the detection of said binding to the binding of antibodies in the control sample with said protein.

34. A method of detecting the presence of Mycobacterial nucleic acid in a sample, said method comprising:

combining a nucleic acid sample with a probe nucleic acid which hybridizes with the sequence of SEQ ID NO:1 or its complement; and

detecting nucleic acid hybridized with said probe.

35. The method of Claim 34, wherein said Mycobacterium is selected from the group consisting of *M. bovis, M. tuberculosis, M. leprae, M. africanum, M. microti, M. avium, M. intracellulare* and *M. scrofulaceum.*

36. The method of Claim 34, wherein said sample comprises mammalian cells and/or body fluid.

37. The method of Claim 34, wherein said probe nucleic acid hybridizes with single 3.25 kb BamH I fragments from *M. bovis* BCG and *M. tuberculosis* H37Rv DNA, but not BamH I-digested DA from either *M. smegmatis* or *M. vaccae.*

38. The method of Claim 34, wherein said detecting is by Southern Blot.

39. The method of Claim 34, wherein said Mycobacterial nucleic acid is amplified by Polymerase Chain Reaction.

40. The method of Claim 39, wherein said amplification uses primers derived from the sequence of SEQ ID NO:1 or homolog thereof.

41. A method of detecting the presence of Mycobacterium in a biological sample, said method comprising;

lysing the cells in said sample;

combining said lysate with antibodies to a protein having the amino acid sequence of SEQ ID NO:2 or an antigenic determinant thereof; and

detecting said antibodies bound to protein in said lysate.

42. The method of Claim 41, wherein said Mycobacterium is selected from the group consisting of *M. bovis, M. tuberculosis, M. leprae, M. africanum, M. microti, M. avium, M. intracellulare* and *M. scrofulaceum.*

43. The method of Claim 41, wherein said lysate is immobilized on a solid support.

44. The method of Claim 43, wherein said solid support is nitrocellulose.

45. The method of Claim 41, wherein said detecting is by a qualitative detection system.

46. The method of Claim 45, wherein said qualitative detection system is a horseradish peroxidase-protein A detection system.

47. The method of Claim 41, wherein said detecting is by a quantitative detection system.

48. The method of Claim 47, wherein said quantitative detection system is a radioimmunoassay.

49. The method of Claim 41, further comprising:
culturing a diagnostic sample to produce colonies of bacteria present therein, whereby said culture represents said biological sample.